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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,537	11/25/2003	Theresa Callaghan	ROC026DIV1	5734

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1655

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,537	<b>Applicant(s)</b> CALLAGHAN ET AL.	
	<b>Examiner</b> Susan D. Coe	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The amendment filed January 23, 2006, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 11-40 are pending.
3. The declaration filed November 7, 2005 and January 23, 2006 has been considered.

### ***Specification***

4. The amendment filed January 23, 2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant has added information that was incorporated by reference. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

### ***Claim Rejections - 35 USC § 112***

5. Claims 11-40 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the previous Office action because the specification, while being enabling for treating inflammation, does not reasonably provide enablement for treating any other disorder.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues the claims are enabled because the use of plant extracts is not unpredictable. This is not persuasive. Plant extract compositions have

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pharmaceutical properties and are used as pharmaceuticals. With any pharmaceutical pursuit there is a large degree of unpredictability. Applicant's claims encompass treating every possible disorder that can be treated topically. These include ailments that are notoriously difficult to treat such as viral infection and skin tumors. Applicant also argues that the declaration of Dr. Tierney shows that the claims are enabled for their full scope. However, the declaration only shows a small number of possible uses from the thousands encompassed by the claims. In addition, the specification must be enabled at the time of filing. The declaration is not considered to show enablement at the time of filing. Applicant also argues that the examiner must point out a specific law that requires applicant to recite a specific benefit. 35 U.S.C. 112, first paragraph, specifically states that the specification must "enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention." As discussed, applicant's specification has not met this requirement for the scope of the claims. The specification does not meet the enablement requirement.

6. Claims 11-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of

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Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claims are drawn to a method for topically administering a feverfew extract that is substantially free of alpha unsaturated gamma lactones. No specific use is claimed; thus, the claims encompass administering the feverfew for thousands of possible uses. However, the specification only discloses that the feverfew extract is able to topically treat inflammation. In analyzing whether the written description requirement is met for genus claims, it is first determine whether a representative number of species have been sufficiently described. In this case, only one use as been described while thousands are encompassed by the claims.

Applicant's specification has only demonstrated that the feverfew extract can be used to topically treat inflammation. This limited information is not deemed sufficient to reasonably convey to one skill in the art that applicant was in possession of all possible uses of the feverfew extract at the time the application was filed. Thus, it is concluded that the written description requirement is not satisfied for the claimed genus.

### ***Double Patenting***

7. Claims 11-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,410,062 for the reasons set forth in the previous Office action.

In response to this rejection, applicant states that a terminal disclaimer will be filed when allowable subject matter is indicated. Thus, at this time, this rejection is still considered valid.

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8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



4-11-06

Susan D. Coe  
Primary Examiner  
Art Unit 1655